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China, Peoples Republic of

Agricultural Situation

Draft Regulation on Risk Assessments

2009

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Report Highlights:

On June 8, the Ministry of Health published a draft regulation designed to implement certain aspects of the new Food Safety Law. This regulation relates to how the Government of China will conduct food safety risk assessments. This GAIN report contains an UNOFFICIAL of translation of these draft regulations.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Beijing [CH1]
[CH]

Summary:

On June 8, the Ministry of Health published a draft regulation designed to implement the food safety risk assessment aspect of the Food Safety Law (CH9019). This draft regulation deals with how and when risk assessments take place and under what circumstances.

The original version of the regulation in Chinese can be found at:

<http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohwsjdj/s3593/200906/41100.htm>

This regulation has been published for Chinese domestic comment. The due date for submission of comments to the Chinese Government is June 20. Other draft implementing regulations have been published as GAIN Reports CH9018, CH9019, CH9040, and CH9051. This regulation has not yet been submitted to the World Trade Organization for comment.

Special thanks go to the Beijing office of the U.S. Food and Drug Administration for their assistance in translating the measure.

This GAIN report contains an UNOFFICIAL translation of the regulation.

BEGIN TRANSLATION**(Draft for Comment)**

To All Units:

The Ministry of Health has published "Regulation for the Administration of Food Safety Risk Evaluation" in cooperation with the application of the Food Safety Law. Public opinions are welcome, so all units and individuals concerned should provide feedback, comments and suggestions by June 20, 2009 by fax or by email.

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Regulation for the Administration of Food Safety Risk Evaluation

1. Objective: To standardize food safety risk evaluation. This regulation is developed based on the Food Safety Law and Food Safety Law Implementation Regulations.
2. Contents: This regulation is used for food safety regulatory agencies in the State Council, national food safety risk evaluation committee and food safety risk evaluation agencies to conduct work related to food safety risk evaluation principle, scope of work, procedure and outcomes.
3. Responsibilities: The Ministry of Health (MOH) under the State Council is responsible for organizing food safety risk evaluation; establishing national food safety risk evaluation expert panels; issuing risk evaluation tasks; taking appropriate surveillance actions, inspection, notification and supervision based on the food safety risk evaluation results.
When related authorities under the State Council provide suggestions on conducting food safety risk evaluation to MOH, they should follow the requirements of related laws and this regulation and provide information and materials.
4. Principle: Food safety risk evaluation is based on surveillance information, scientific data and other related information; and follows principle of science, transparency and are done on a case-by-case basis.
5. The national food safety risk evaluation committee should conduct risk evaluation based on this regulation. It (the committee) can authorize related technical agencies to undertake collection, handling and analysis of scientific data, technical information and test results. The fee for risk evaluation is paid by the health authorities under the state council.
6. Independence: The national food safety risk evaluation committee and agencies conducting risk evaluations should independently conduct risk evaluation to ensure the results are scientific, objective and judicious.
7. Evaluation scope of work: Under following situation, the food safety risk evaluations can be done with approval by Ministry of Health:
 - i. To provide evidence for developing or amending national food safety standards;
 - ii. To analyze food safety surveillance results or review reports that show potential safety risks. After testing, further food safety risk evaluation is believed to be needed.
 - iii. The Ministry of Agriculture (MOA), Administration for Quality, Supervision, Inspection, and Quarantine (AQSIQ), Ministry of Commerce (MOFCOM), State Food and Drug Administration (SFDA) propose food safety risk evaluation and provide related information and materials.
 - iv. Other situations where the Ministry of Health identifies the needs of risk evaluation based on laws and regulations.
8. The Ministry of Agriculture (MOA), Administration for Quality, Supervision, Inspection, and Quarantine (AQSIQ), Ministry of Commerce (MOFCOM), State Food and Drug Administration (SFDA) can propose risk evaluation and provide information and materials based on following needs:
 - i. Finding certain food, food raw material, food additives, food related products that have potential safety risk;
 - ii. Using new science and technique developments, the need to re-evaluate certain food or the risk factors of food become clear; and
 - iii. Need to identify the priority areas of food safety regulatory administration and priority products.
9. When the related authorities under the State Council propose risk evaluation, they should provide a "proposal of risk evaluation program" and provide food safety risk surveillance information, scientific data, and other related information.

10. In relationship to the consumption of agriculture products, based on laws and regulations, MOA should notify MOH of the quality and safety risk evaluation results of existing agriculture products.
11. Situations of no evaluation: Under following situations, MOH can decide not to conduct evaluation if the national food safety risk evaluation committee comes to the following conclusions:
 - i. There is illegal behavior during the production process that can be solved by taking action in accordance with the law.
 - ii. The food safety risk is low or problems can be solved by taking simple risk management measures and it is not necessary to conduct a full evaluation.
 - iii. There is an international risk evaluation conclusion and the conclusion is suitable for the Chinese dietary exposure mode.

In the above situations, if new scientific data and information provide evidence of the need for a risk evaluation, the MOH should make new decision on conducting risk evaluation.

12. MOH should identify the national food safety risk evaluation plan and priority evaluation programs based on the items #7 and #8.
13. Clarification of tasks: When health authorities issue food safety risk evaluation tasks, it should collect the following information from authorities who propose the evaluation:
 - i. The nature of the hazards, concerned type of food, quantity and distribution of the food;
 - ii. The measure of the hazards entering the food and its contents in the food;
 - iii. The potential health problems caused by the hazards;
 - iv. The population and number impacted by the hazards;
 - v. The existing domestic and international regulatory measures; and
 - vi. Other information related to risk evaluation.
14. Issue tasks: MOH tasks issued to the national food safety risk evaluation expert committee through "risk evaluation assignment". The assignment should include the objectives of the risk evaluation and the problems that need to be solved and the format of outcome.
15. Develop evaluation plan: The national food safety risk evaluation expert committee should propose a risk evaluation implementation plan based on the tasks and report to the State Council. If supplemental information is needed, MOH should provide suggestion on data and information collection.
16. Implement evaluation: National food safety risk evaluation expert committee conduct evaluation based on the implementation plan and follow the process of hazards identification, hazards character description, exposure evaluation and risk characters description.
17. Risk communication: During the risk evaluation, the risk evaluation agencies that implement the tasks should submit work progress reports based on the requests of national food safety risk evaluation committee and MOH. For those that need further supplement data during the risk evaluation, the national food safety risk evaluation committee should report to MOH and provide suggestions.
18. Evaluation results: The agencies who conduct risk evaluation should provide the evaluation results within the time frame requested by the national food safety risk evaluation committee. After reviewed by national food safety risk evaluation committee, the results will be reported to MOH. National food safety risk evaluation committee and risk evaluation agencies are responsible for the evaluation results and reports.
19. Emergency evaluation: Under the following situations, MOH can request that the national food safety risk evaluation committee immediately study and research. For the items needing risk evaluation, the national food safety risk evaluation committee

should establish a temporary working group and develop an emergency evaluation plan:

- i. To deal with significant food safety accidents;
 - ii. The publicize highly concerning food safety problems which need quick responses;
 - iii. Are needed by regulatory agencies and proposed for emergency evaluation;
 - iv. Are needed to deal with international trade disputes; and
 - v. Other food safety affairs that should be solved through risk evaluation
20. Conducting evaluation: temporary working group should conduct risk evaluation based on the emergency evaluation process and emergency evaluation plan and report to MOH on time.
21. Publish results: MOH publishes food safety risk evaluation results based on related laws. The risk evaluation results should be explained by the national food safety risk evaluation committee.
22. The definitions of this regulation are:
- Food safety risk evaluation: refers to scientific evaluation of the potential negative impact on human health caused by food and biological, chemical and physical hazards in food additives. It includes hazard identification, hazard character description, exposure evaluation and risk character description.
 - Hazards: the biological, chemical or physical factors in food or food product, which cause potential harmful effects to health.
 - Hazard identification: refers to qualitative description of certain hazards in food that cause potential harmful effects to health.
 - Hazard character description: refers to qualitative and quantitative analysis on hazards' dose-effect relationship or the mechanism of the hazards.
 - Exposure evaluation: the qualitative and quantitative analysis of hazards intake among various populations.
 - Risk characterization description: comprehensive analysis of the severity and possibility of hazards negative impact on health based on the results of hazard identification, hazard characteristic description and exposure evaluation.
23. This regulation is to be interpreted by MOH. It is implemented from the date of publishing.

Attachment:

Proposal for food safety risk evaluation tasks

Name of task			
Proposing Agency		POC and contact info	
Suggested evaluation process*	Normal process () Emergency process ()		
Hazard description	Name of hazard		
	Method of entering the food chain		
	Type of food that was contained		
	Frequency of occurrence		
	Content in food		
	Potential impact population		
Situation information and description	(The source, time and verification of the affairs)		
Potential impact on health			
Existing domestic or international regulatory measures			
Other information			

*: If suggesting an emergency process, please provide background information and rationale.

Name of proposing agency (signature)

Date:

END TRANSLATION